

# **DIGITAL BRAIN ELECTRIC ACTIVITY MAPPING**

## **EEG-32**

**MANUAL BOOK**

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### **CAUTION**

In the United States, Federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.

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## Chapter 1 General

### 1.1 Overview

The Digital Brain Electric Activity Mapping transits brain bioelectrical activity into marked intuitionistic image, which is a noninvasive, advanced and scientific method on intracranial diseases diagnosing and quantitative analysis of brain functions. Characters of this device are as follows:

- Help to emphasize and recognize EEG partial features.
- Recognize the subtle features that easy to be ignored by visual inspection.
- Display brain activities in intuitive images, convenient to academic communication, especially for the unprofessional people.
- Evaluate the abnormal conditions in the traditional EEG and the unexplained situations by visual inspection.

Main structure: The device samples EEG signals by electrodes, signals pass through integrated amplification, A/D conversion, microcomputer automatic analysis, FFT conversion, to form brain electrical activity mapping (BEAM), and the color depth represents power distribution. The result is displayed on the screen or output by printer.

Specification: EEG-32

Composition: recorder, USB cable, lead cable, EEG electrodes, electrode cap and software (a CD).

Application range: inspection of diseases such as epilepsy, intracranial inflammation, cerebrovascular disease, brain tumor.

Intended use: hospital and scientific research. The device can sample and extract brain wave group of patient, therefore providing EEG signal records for medical institutions.

### 1.2 EMC Precautions

---

#### WARNING

1. If the device does not function properly during use, be sure to eliminate the adverse effects before continuing to use it. In response to this situation, the corresponding precautions are given in this manual.

- 
2. The device or system should not be used near or stacked with other devices. If it must be used near or stacked with other devices, it should be observed and verified that the device is working normally under the configuration it is using.
  3. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the device or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the device or system.
- 

#### **The effects of radiated electromagnetic waves:**

The use of a mobile phone may affect the operation of this device. When installing the device, be sure to remind people around to turn off mobile phones and small radios.

#### **The effects of impact and conductive electromagnetic waves:**

High-frequency noise from other equipment can enter the device through the AC outlet identify the noise source and, if possible, stop using the equipment. If the equipment cannot be deactivated, use noise cancellation equipment or take other measures to reduce the impact.

#### **The effects of static electricity:**

Static electricity in a dry environment (indoor) can affect the operation of the device, especially in winter. Before using, humidify the indoor air or discharge the static electricity from the cable and the operator.

#### **The effects of lightning:**

If there is lightning nearby, it may cause a voltage surge in the device. If you are concerned about danger, disconnect the AC power plug and use the internal power supply.

### **1.3 Symbols**

You may see the following symbols used in this device.

|  |   |
|--|---|
|  | Type BF applied part                          |
|  | Class II equipment                            |
|  | USB interface                                 |
|  | Attention! Refer to the accompanying document |



Attention! Refer to the accompanying document

## 1.2 Requirements

Users need to use their own computer and printer that satisfy the following requirements:

CPU: at least Pentium 4

Memory Card: 512M

Motherboard: Support USB2.0, Recommend to use Intel chipset motherboard

Hard drive: More than 40 GB

Display card: More than 64 MB

Resolution ratio: 1024\*768

Printer: 300dpi color printer

Screen: ≥17 Inch color display screen

Operation System: WINDOWS XP, WINDOWS 7, WINDOWS 8 (32Bit)

Color: 24-bit color or higher

Font: normal font

Interface: USB2.0

## Chapter 2 Technical Specification

1. **Normal working condition:**
  - a) Temperature: +5 °C ~ +40 °C
  - b) Relative humidity: ≤85%
  - c) Power supply: DC 5 V
  - d) Atmospheric pressure: 700 hPa ~ 1060 hPa
2. **Transport and storage condition:**
  - a) Temperature: -20 °C ~ +55 °C
  - b) Relative humidity: ≤90%
  - c) Atmospheric pressure: 700 hPa ~ 1060 hPa
3. **Calibration voltage:** 50 μV; error: ±5%
4. **Scan speed:** 30 mm/s; error: ±5%
5. **Noise level:** ≤5 μV
6. **Common-mode rejection ratio:** ≥90 dB
7. **Input Impedance:** >10 MΩ
8. **50 Hz interference suppression:** ≥30 dB
9. **Frequency Characteristics:** No distortion occurs when inputting 0.8 Hz ~ 30 Hz, -3 dB, 50 μV sinusoidal AC signal.
10. **Resistance to polarization voltage:** The deviation should not be greater than ±5% when adding ±300 mV DC polarization voltage.
11. **Channels:** 32 leads EEG
12. **Safety classification:** Class II, type BF applied part

## Chapter 3 Software and Hardware Setup Wizard

### 3.1 Software setup wizard

First of all, put the CD-ROM containing software package into the drive, double-click the installation package with left button of mouse, the "Select Setup Language" dialogue box as shown in Figure 3-1 will pop up, choose a language and click "OK", then the dialog box as shown in Figure 3-2 will appear.



Figure 3-1



Figure 3-2

To continue, click "Next" to pop up the dialogue box as shown in Figure 3-3. If you would like to select a different folder, click "Browse" (the default setting is recommended). Click "Next" 3 times, the dialogue boxes as shown in Figure 3-4, 3-5, 3-6 will appear in turn.



Figure 3-3



Figure 3-4



Figure 3-5

In the "Ready to Install" dialogue box as shown in Figure 3-6, click "Install" button.



Figure 3-6

When the dialogue box as shown in Figure 3-7 appears, click "Continue Anyway".

When the dialogue box as shown in Figure 3-8 appears, click "Finish" to complete the software installation.



Figure 3-7



Figure 3-8

### 3.2 Hardware Wizard

After installing the software, connect the ECG amplifier and the strobe light respectively to the USB interface of computer by two data lines, then the computer will prompt for finding a new hardware, as shown in Figure 3-9.



Figure 3-9

Choose the third option “No, not the time” and click “Next” to continue. In the dialogue box as shown in Figure 3-10, click “Next”, in Figure 3-11, click “Continue Anyway”.



Figure 3-10



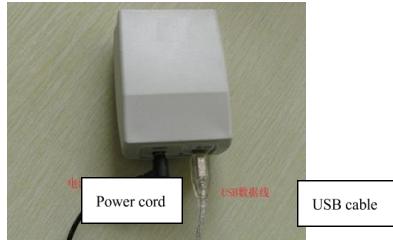
Figure 3-11

When the dialogue box as shown in Figure 3-12, click “Finish” to complete the hardware installation.



Figure 3-12

!Note: After clicking “Finish”, the computer will prompt for finding a new hardware again. And you can follow the above steps and install it one more time. Then the hardware drive will be installed completely.



### 3.3 Uninstall The Software

#### Method 1

Click “Start” menu, find the installation package in the “All Programs”, then click the icon  to uninstall the software.

#### Method 2

Find the software installation directory (usually installed by default under the C drive), open the installation directory to find the icon  and double-click it to uninstall the software.

## Chapter 4 Operation Guide

### 4.1 Placement of Electrodes

This system uses silver chloride channel electrode, which is immersed in 5% saline solution during use. Rinse the electrode with clean water after use and air dry. Put it in a container with lid for storage to prevent exposure to protect the chlorinated layer of electrode.

The placement of electrodes should be in accordance with the international 10-20 system. The left side is odd number, right side is even number. Refer to the Appendix Placement of electrodes for details.

### 4.2 Software Introduction and Operation System

Name of software: EEG 32

Software specification: none

Software version: V5.0.4

Rules of software naming: "Major enhancive upgrade". "Minor enhancive upgrade". "Corrective upgrade". "Build"

You can see the version in the "Help" of the software.

Algorithm involved:

Name: CMSEEG

Type: mature algorithm

Application: transit brain electrical activity to intuitive images and then analyzing

Clinical function: The analysis of patient's brain wave groups by this algorithm can emphasize and recognize EEG partial features, and identify the subtle features that easy to be ignored by traditional visual inspection. It is used for the inspection of diseases such as epilepsy, intracranial inflammation, cerebrovascular disease, brain tumor, providing reliable basis for clinical doctors.

Turn on the computer. The LED on the top right corner is the power indicator light, after turning on the device, the indicator light lights in green. Double click the executable program icon of the software, the computer enters the operational system, as shown in Figure 4-1.

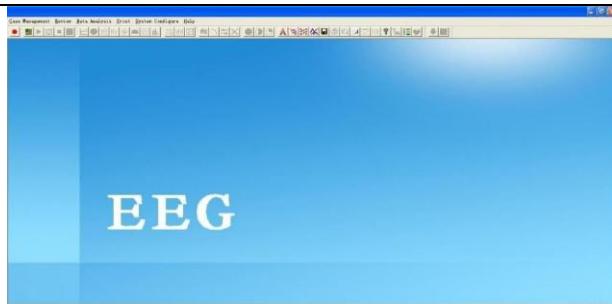


Figure 4-1

Select the menu of "Case Management" > "New Patient" to enter the interface as shown in Figure 4-2.

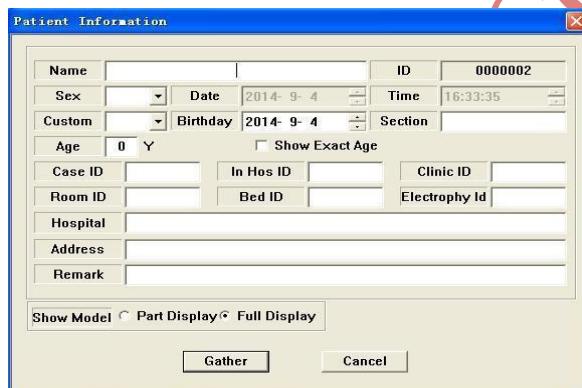


Figure 4-2

Physician can input parameters according to the patients' condition. The name item could input by English or Chinese. Press "Ctrl+Space" in keyboard to switch into Chinese input mode, and then input patient's name. After inputting the birth date, the device will calculate patient's age automatically, when "Show Exact Age" is selected, the age display can be accurate to days. Physician can choose the display mode of gathering ("Full Display" or "Part Display"). Click "Gather" and enter intro gathering interface.

### 4.3 Gathering Control Panel

In the gathering interface, the left is the acquired real-time waveform of the patient's EEG and the right is the gathering control panel that displaying various of evoked events and controls the gathering methods. As shown in Figure 4-3, Figure 4-4 and Figure 4-5.

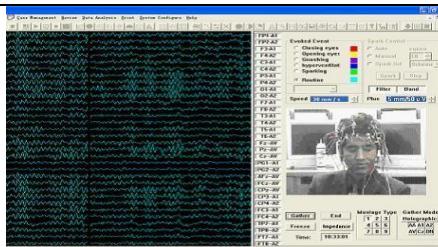


Figure 4-3

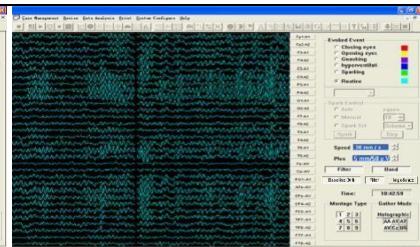


Figure 4-4

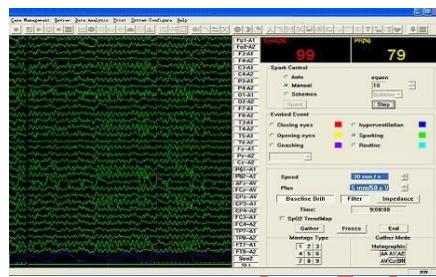


Figure 4-5

#### "Evoked events":

Click the evoked event by left button of mouse (including the events in the drop-down box added by user), the recorded EEG will be marked with specified color with corresponding name of evoked event, which is convenient to the analysis by physicians. If user does not add any evoked event, the drop-down box is gray and unable to use. Refer to the following content for how to add evoked event.

#### "Spark control":

Connect the strobe light with USB line, select "Sparking" as evoked event and choose one of the following strobe light control types.

"Auto": system controls the frequency from low to high automatically;

"Manual": manually control the frequency;

"Scheme": select one of scheme from the drop-down list at the right side.

After selecting the control type, click "Spark" button, the strobe light starts working. In the "System Setting" -> "Gathering Setting", if "Spark frequency channel" is selected, the gathering interface will show the flickering frequency, and click "Stop" button to end.

#### "Speed" and "Plus":

Adjust recording speed and amplitude of EEG waveform during gathering.

#### "Baseline drift" and "Filter":

The filters could reduce image error due to baseline drift and filter out AC work frequency. Except in the environment with good signal and small interference, it is generally recommended to use the filters to obtain better images.

#### "Gather", "Pause", "End", "Freeze":

"Gather": begin to record the EEG data into file

"Pause": display the changes of EEG in real-time without saving the data

"Freeze": freeze the image but continue to gather and save EEG data

"End": finish gathering EEG data and automatically return to the review interface of the waveform just gathered.

#### "Impedance":

Click "Impedance" button to start the impedance detection function. If the electrode is not connected to the skin or the connection is not good, the lead-off indicator LED will light.

#### "Time":

It displays the current time of system, after clicking "Gather" button, it displays the total time of gathering.

### 4.4 Review Interface and Operations

Click "End" to stop EEG gathering and return to the review interface. See Figure 4-6 and Figure 4-7.

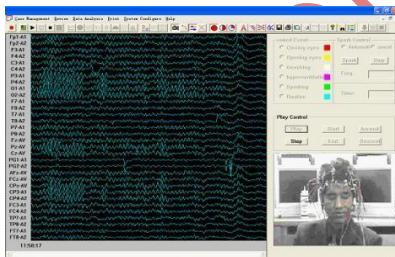


Figure 4-6

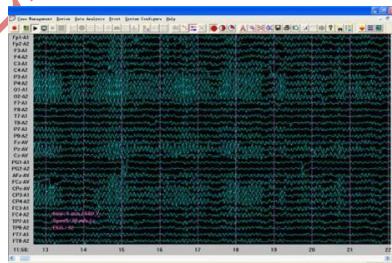


Figure 4-7

"Play": play the EEG waveform from starting.

"Stop": stop playing.

Under the non-playing situation:

"Start": back to the starting point of the EEG waveform;

"End": back to the end point of the EEG waveform;

"Ascend" and "Descent": adjust the gain of the EEG waveform.

Click button to play EEG waveform from the starting to the end, and click button to stop.

### **Function 1: Time division**

Select "Review" -> "Divide Time" or click button , the waveform of one second could be divided into five parts to display, refer to Figure 4-8.

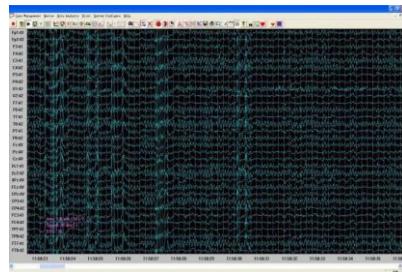


Figure 4-8

### **Function 2: Adjust by right button of mouse**

Move the mouse to any point on the EEG waveform, click right button of mouse to pop up a menu to adjust auto play mode and speed, display speed and amplitude.

In the review interface, the current setting of amplitude, display speed, lead information is displayed at the bottom left corner, as shown in Figure 4-9.

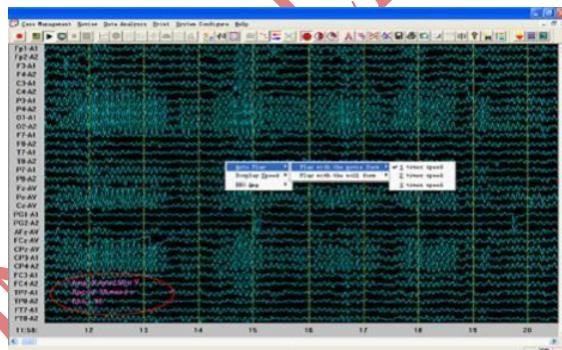


Figure 4-9

### **Function 3: Leads per Screen**

Select menu "Review" -> "Montages per Screen" or click the buttons as described below:

-  button is used to display 16-channel EEG in the same screen.
-  button is used to display 8-channel EEG in the same screen.
-  button is used to display 4-channel EEG in the same screen.

#### Function 4: Full-Screen display

In the review interface, double click the name of a lead, its waveform will be displayed in full screen, as shown in Figure 4-10.

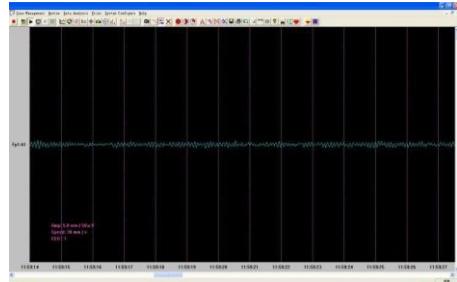


Figure 4-10

#### Function 5: Marks/Events

##### 1. Mark List

Physicians can add marks where it is necessary, method as follows:

Select menu of "Review" -> "Add Marks" or click the toolbar button , then click left button of mouse at where you need to add a mark, a dialogue box as shown in Figure 4-11 will pop up, and the corresponding location appears a mark .



Figure 4-11

Inputting information in "Remark" and click "Modify" button, the operation of adding marks is finished.

Modify the existing marks: select "Review" -> "Marks/Events" or click button , the same dialogue box as Figure 4-11 pops up, select the mark you want to modify, and input the contents in "Remark", then click "Modify" to finish the modification. Click to find the mark location, click

↑ and ↓ to select the up/down mark. When user opens the case next time, click button to display or hide the added marks.

## 2. Event List

Select menu of "Review" -> "Marks/Events" or click button , a dialogue box as shown in Figure 4-11 will pop up. Click "Event List" to display the event list as shown in Figure 4-12. The window shows the information (name, start time, duration) of every evoked event.

Select an event by clicking mouse or ↑ and ↓ buttons, then click to locate the waveform that the event occurred.

| ID | Time     | Remark      | Duration |
|----|----------|-------------|----------|
| 1  | 11:58:09 | Routine     | 0:01:48  |
| 2  | 11:59:57 | Sparking    | 0:01:15  |
| 3  | 12:01:12 | Routine     | 0:00:46  |
| 4  | 12:01:58 | Closing ... | 0:00:07  |
| 5  | 12:02:05 | Routine     | 0:00:07  |

Figure 4-12

## Function 6: Select segment

Sometimes, physicians need to choose a part of the EEG waveform for analysis, the method is as follows:

Move the mouse to the beginning of the EEG waveform to be analyzed, and click the left button of mouse, then move the mouse to the end of EEG waveform, press "Shift" on the keyboard, at the same time, click the left key of mouse, the EEG waveform segment is then selected. The chosen EEG segment is displayed in a different color. Each time user can select 10 segments at most, and each segment should be longer than 1 second. Refer to Figure 4-13.

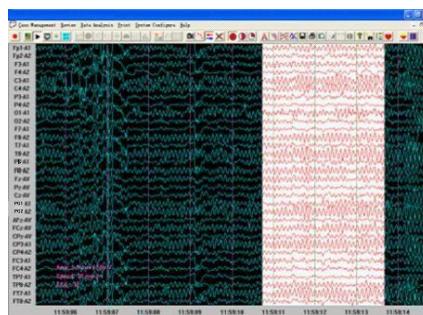


Figure 4-13

### **Function 7: Save segment**

Click "Case Management" -> "Save Segment" to save the selected EEG segment. If there are multiple segments selected, they will be saved as one EEG segment. Input the name of the segment to be saved, click "OK" to save it under the folder of this case, as shown in Figure 4-14.



Figure 4-14

### **Function 8: Cancel segment**

If you want to cancel the latest selected segment, select menu "Review" -> "Cancel one Segment"

or click tool button

### **Function 9: Data analysis**

After selecting one or more segments, select menu "Data Analysis" -> "Data Analysis" or click

button to start processing the selected EEG segment for FFT transformation and interpolation.

### **Function 10: Analysis views**

#### Power Spectrum Graph

After data processing is finished, the EEG waveform can be analyzed. Select menu "Data Analysis"

-> "Power Spectrum Graph" or click button to enter the power spectrum interface, as shown in Figure 4-15.

This interface is to observe power spectrum distribution. Clicking left button of mouse on any small graph could magnify it.

Clicking right button of mouse on the enlarged graph could show the frequency and power spectrum intensity where you have clicked.

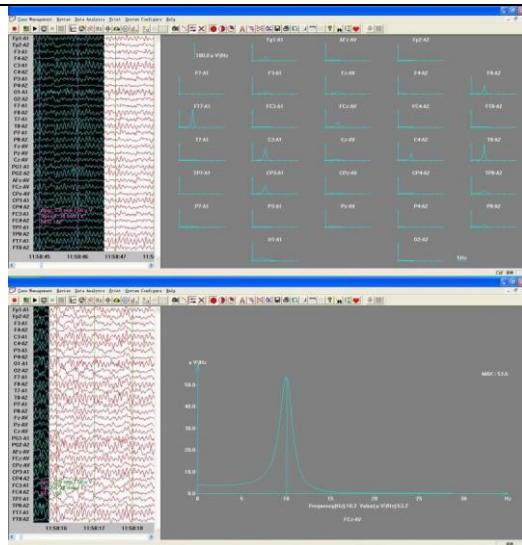


Figure 4-15

### BEAM

Select menu “Data Analysis” -> “BEAM” or click button to enter the following interface as shown in Figure 4-16.

The left part of this interface displays the patient’s EEG, and the right part is the BEAM top view.

button is used to switch between the absolute layer and relative layer of the BEAM.

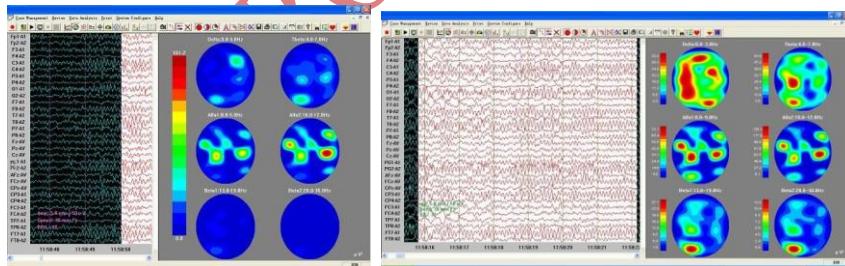


Figure 4-16

### Compressed Spectrum Graph

Select menu “Data Analysis” -> “Compressed Spectrum Graph” or click button to enter the following interface as shown in Figure 4-17. The physician can set the compressed spectrum graph according to menu tips, then click “Ok” to enter the interface as shown in Figure 4-18.

This menu displays the compressed spectrum graph between any two leads.

X axis represents the frequency, the unit is Hz.

Y axis represents the power, the unit is pV<sup>2</sup>/Hz.

Z axis represents the dimension, it can be decided by the physician.

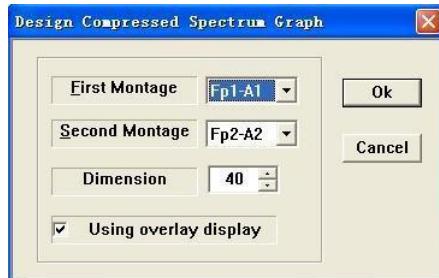


Figure 4-17

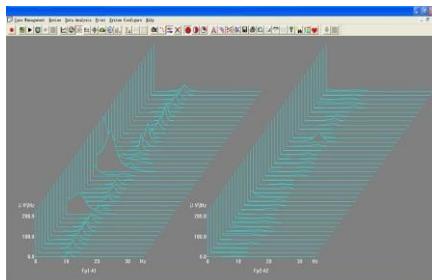


Figure 4-18

### Monochromatic View BEAM

Select menu “Data Analysis” -> “Monochromatic View BEAM” or click button to enter the following interface as shown in Figure 4-19.

The left part of this menu is the patient’s EEG. The right part is the patient’s BEAM of 1~30 Hz.

Click button to switch between absolute mode and relative mode of the BEAM.

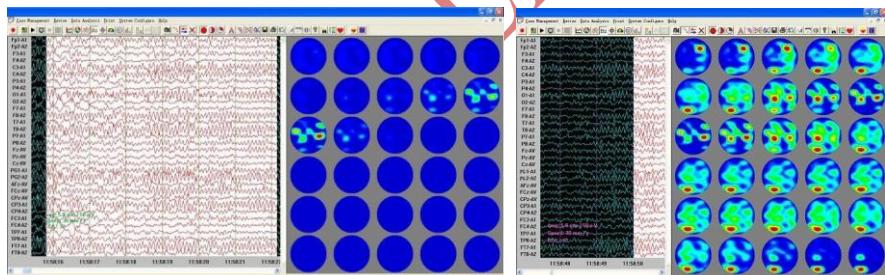


Figure 4-19

### Three-Dimensional Rotary BEAM

Select menu “Data Analysis” -> “Three-Dimensional Rotary BEAM” or click button to enter the following interface as shown in Figure 4-20. The right part of the menu is the patient’s three-dimensional stereoscopic BEAM. Click and hold the left button of mouse to drag each BEAM to rotate it at any angle, which facilitates the physician to locate the lesion correctly.

Click button to switch between absolute mode and relative mode of the BEAM.

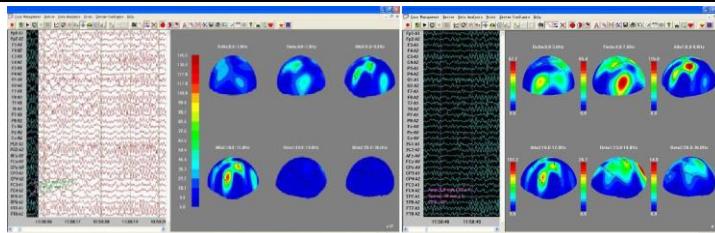


Figure 4-20

### Side View BEAM

Select menu “Data Analysis” -> “Side View BEAM” or click button to enter the following interface as shown in Figure 4-21. The interface displays the patient’s BEAM in side view.

Click button to observe the patient’s side view BEAM from left or right side.

Click button to switch between absolute mode and relative mode of the BEAM.

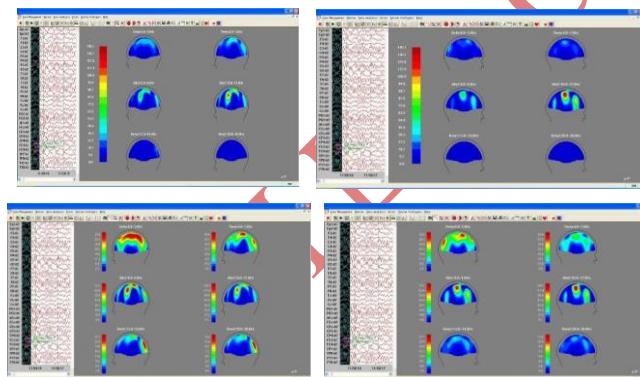


Figure 4-21

### Numerical BEAM

Select menu “Data Analysis” -> “Numerical BEAM” or click button and enter the following interface as shown in Figure 4-22. This menu is numerical BEAM.

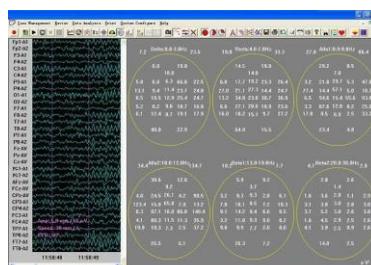


Figure 4-22

## Spectrum Histogram

Select menu “Data Analysis” -> “Spectrum Rectangle Graph” or click button  to enter the following interface as shown in Figure 4-23. Clicking any small chart could magnify it.

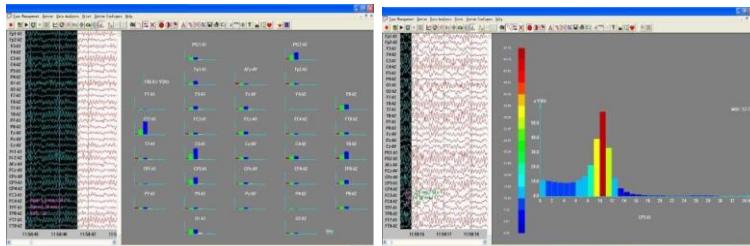


Figure 4-23

## Function 11: Sleep Analysis

Click button  to enter the following interface as shown in Figure 4-24. This figure is the dialog box for sleep analysis setting (Note: Only when the collected waveform is longer than 5 minutes, can the data be used for sleep analysis)

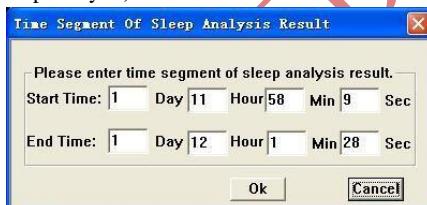


Figure 4-24

Set the time length and click “OK” to start the sleep analysis. After analyzing, select menu “Data Analysis” -> “Sleep Process Graph” or click button  to view the analyzing graph, as shown in Figure 4-25.

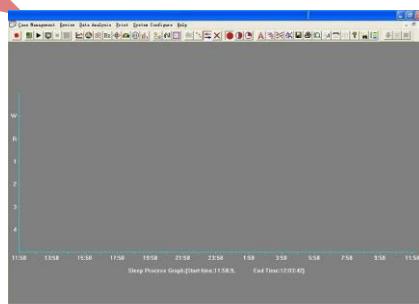


Figure 4-25

Select menu “Data Analysis” -> “Sleep Analysis Report” or click button  to view the report of sleep analysis, as shown in Figure 4-26.

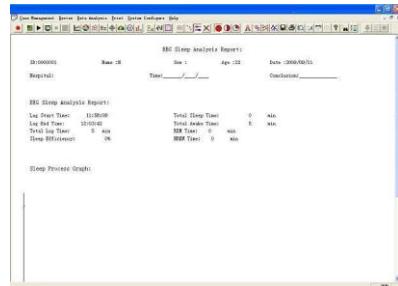


Figure 4-26

### Function 12: Simple Ruler

When reviewing a case, press and hold the “Ctd” button, click the left button of mouse and move it, the area where the mouse has moved could be displayed, including the horizontal and vertical distance (mm), the horizontal coordinate means voltage ( $\mu$ V), the vertical means frequency (Hz). A ruler is divided by several ruler units of fixed spacing, the unit can be set to 1-100 mm in the system setup. Refer to Figure 4-27.

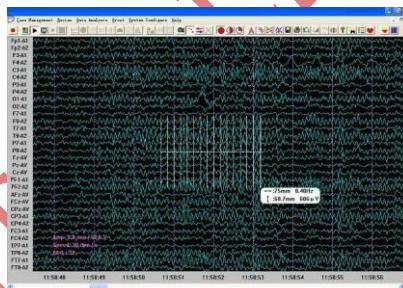


Figure 4-27

### Function 13: Proportional Scale

In the reviewing interface, when user choose to view one or more EEG waveform in the print preview, there is a proportional scale displayed in the left button. Because the printer's resolution is not fixed, the millimeter shown on the computer will be different from the paper. The horizontal scale represents 5 mm in the actual, and the vertical scale represents 20  $\mu$ V. It provides reference for doctors to observe the waveform on paper. Shown as Figure 4-28.

Figure 4-28

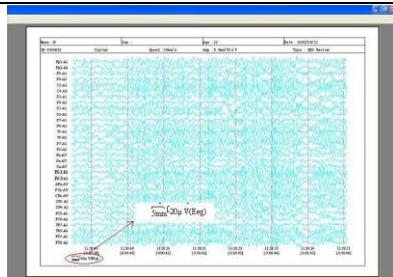


Figure 4-28

#### Function 14: Automatic Measure

Double click the left mouse button in the EEG waveform area, a dialog box of automatic measurement to the waveform as shown in Figure 4-29 will appear. There are 3 “+” displayed, select a “+” and drag the mouse, the displayed gain of waveform, period and frequency will be changed accordingly. You can roll the mouse wheel to zoom in or zoom out the vertical display scale. To zoom in or zoom out the horizontal display scale, press and hold “Ctrl” button, and roll the mouse wheel.

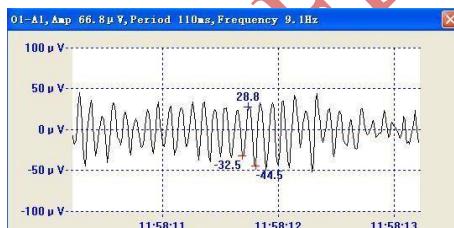


Figure 4-29

#### Function 15: Frequency Band Division

Select menu “System Configure” -> “Frequency Seg. Partition” or click button to enter the following interface as shown in Figure 4-30, The physician can be divide frequency segment according to this menu. Click “OK” to save, the system will remind user if the setting is out of the range. The set parameter is only valid for running program.



Figure 4-30

## **Function 16: Lead Setup**

Select menu “System Configure” -> “Montage Ways” or click button  to enter the following interface as shown in Figure 4-31. The instructions of lead setup as follows:

Change Lead Name:

Double-click a lead with left mouse button to pop up a dialog box of modifying lead name. Edit a name and click “Ok” to save, click “Cancel” to cancel the operation. The name of lead will appear in gathering interface and review interface.

Add or Remove Channels:

In the channel list, click a lead and drag it out of the list, then the lead is deleted. If you need to add a lead, use the mouse to click any two electrodes to connect them. After finishing the setting of 16 leads EEG, click "OK" to display and save the set lead mode. When user opens the case next time, the set lead mode by user will be displayed (The first two modes are default, and can't be changed by user).

**⚠ Note:** When creating a new patient case, the current lead mode are linked to this case, and the lead names are saved. When user opens this case and wants to change the lead mode, there will be a dialogue box prompting user whether to change the lead mode of current case, if user selects "OK", the lead mode of current case and its linked setting will be changed, if user selects "Cancel", the current lead mode will be still changed, while the linked setting will not be modified.

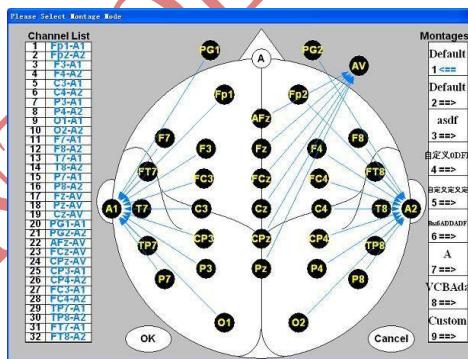


Figure 4-31

## **Function 17: Filter**

Select menu “System Configure” -> “Filter Design” or click  button to enter the following interface as shown in Figure 4-32. In this menu, the physician can set filter according to the patient’s EEG to clear EEG’s disturbance and artifact. Click “Use Filter” to display the filtered EEG waveform.

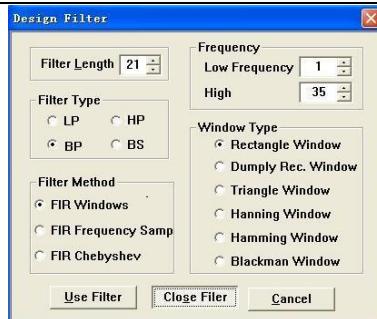


Figure 4-32

### Function 18: System Setting

In this part, we can set hospital information, review parameters, gathering parameters, color parameters, events, strobe event and terminologies.

#### Hospital Setting

The software will automatically fill in the items according to the hospital information input in this menu when it is necessary to enter the same information, to avoid repeated inputting. Select menu "System Configure" → "System Setting" → "Information Setting" and Figure 4-33 dialog box will appear.

Hospital information can be selectively entered and printed as necessary. Refer to the report setting for details.

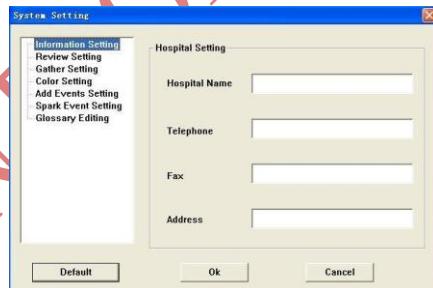


Figure 4-33

#### Review Setting

The review interface is displayed in accordance with the parameters set in this menu, whether it is the overall viewing or detail observation, parameters can be set according to necessary.

Select menu "System Configure" → "System Setting" → "Review Setting" and Figure 4-34 dialog box will appear.

The displayed parameters can be set to control the display effect.



Figure 4-34

The corresponding displayed parameters in review interface is shown as Figure 4-35.

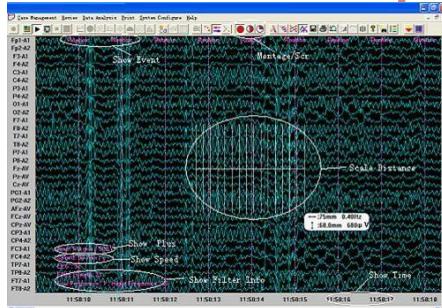


Figure 4-35

"Show Speed": Control the display speed waveform.

"Mtg.Scr.": Control the number of leads in one screen. "ALL Montages" means displaying all-lead EEG waveform, "1/2 Montages" means displaying half of all-lead EEG waveform, "1/4 Montages" means displaying quarter of all-lead EEG waveform.

"Play Speed": to choose the play mode and speed. It can be set in the review interface after clicking right button of mouse, which is more quickly, but the setting will not be saved.

"Show Event": The display style of evoked events. Including "unknown", "show at changed", "show at per second".

"Shield Mtg.": to control the display style of or whether to display the leads that shielded in gathering, the setting includes "No shield" (normal), "show line" and "unshown".

"Show Time": switch the display style between absolute and relative time, including "Show By Second" and "By HH:MM:SS".

"Scale inter.": parameter settings of Function 11.

"Show Filter Info.": After using the filtering, the filter information will be showed on the lower left corner of review interface and the lower right corner of the preview interface.

"Show Plus": Adjust the amplitude of EEG waveform. It can be set in the review interface after clicking right button of mouse, which is more quickly, but the setting will not be saved.

Windows XP: The waveform reviewing is displayed in full-screen by sovereign mode.

### Gather Setting

You can set the time of data in the gathering, the number of leads, prompt of breathing, as well as the limited gathering time (it gathers a fixed length of waveform, and the program will automatically end). Meanwhile, you can choose the reference lead for displaying, and the corresponding waveform will be drawn during gathering.

Select menu "System Configure" → "System Setting" → "Gather Setting" and Figure 4-36 dialog box will appear.

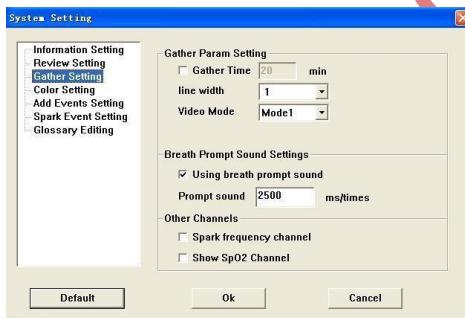


Figure 4-36

"Gather Time": When gathering time achieves this value, the system will stop gathering automatically and return to the review interface. Select this item otherwise it doesn't work.

"line width": Control the width of waveform line both at gathering and reviewing time.

"show montage": Control displayed lead types in one screen at gathering and reviewing time.

"Spark frequency channel": Show the waveform of strobe frequency channel under gathering and review interfaces.

### Color Setting

The colors here, including background color, text color, colors of all kinds of mark lines, and color of the waveform corresponding to each evoked event and the reference lead, controls all color changes under review and gathering interfaces, which is convenient to unified management.

Select menu "System Configure" → "System Setting" → "Color Setting" and Figure 4-37 dialog box will appear.

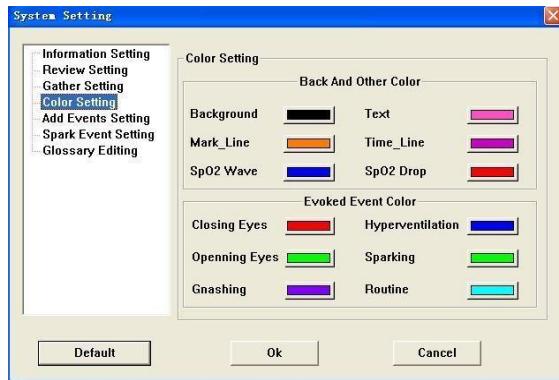


Figure 4-37

In this page, you can set background color, text color and so on. The operation is as follows:  
Click the color button which you want to change, it will pop up a color palette, choose one color and click "Ok".

**⚠ Notice:** To distinguish all kinds of lines, please do not set the same color or similar color.

### Add Events

Events added will be used when gathering. Except the events included in the software, user could also use customized evoked events for gathering, and the color of waveform will be displayed in accordance with the settings in this dialog box.

Select menu "System Configure" → "System Setting" → "Add Events Setting" and Figure 4-38 dialog box will appear.

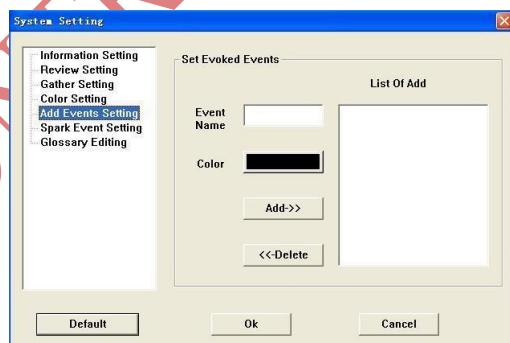


Figure 4-38

User could add customized evoked event, and modify its name and color (Figure 4-37), the operation instructions as below:

Click the edit box next to the "Event Name" and input the name of the adding event, click the color button to choose a proper color, then click the "Add" button to add it to the event list; if you need to delete an event, you can select the event item to be deleted in the event list and click "Delete" button, then click "Ok" to save the operation.

### **Strobe Event Setting**

During gathering, select "Sparking" as evoked event, and choose a proper scheme, then click "Spark", the strobe light will work in accordance with the settings of this dialog box.

Select menu "System Configure" -> "System Setting" -> "Spark Event Setting" and Figure 4-39 dialog box will appear.

After changing the frequency value, user need to click the value to make it under selected state (displayed in blue), then click "Save" to save the operation, otherwise, the modification of frequency may be invalid.

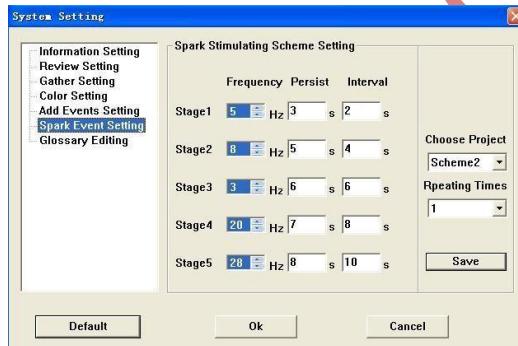


Figure 4-39

Select a scheme except "Scheme 1" to edit, click "Save" to save the operation. Use this scheme when choosing the "Sparking" as evoked event during gathering.

Click "Default" setting, all information in this interface will be displayed by default values. Click "Ok" to save it. If you open the case again, all the information is the same as the default.

### **Terminologies**

It stores some commonly used terminologies. When editing reports, click the items to input into the report, which is very convenient. (See Function 20: Report Setup and Print for details).

Select menu "System Configure" -> "System Setting" -> "Glossary Editing" and Figure 4-40 dialog box will appear.

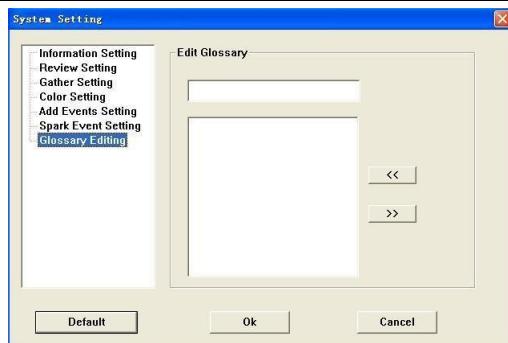


Figure 4-40

Add: Input a terminology in the edit box, and click the **<<** button to add it to the below list. Click "OK" to save the operation.

Delete: Select a terminology in the list and click **>>** button to delete it. After editing, click "OK" to save your setting.

Invoke: When editing the report, double-click the left button of mouse in the editable area to invoke the terminologies.

Click "Default" setting, all information in this interface will be displayed by default values. Click "OK" to save it. If you open the case again, all the information is the same as the default. (Note: Each time you set the parameters, it will come into effect the next time you open it.)

#### Function 19: Calibration

**⚠ Note: The calibration is only used when product leaving the factory or in quality supervision by related institutions.**

Click  button on the toolbar to enter the calibrate interface (Figure 4-41), input the password to enter the calibration system (**The calibration must be processed by system maintenance personal by using standard signal source, non-maintenance personal shall not do the calibration, because improper operations may damage the data in the device, then causing abnormal working**). The signal source should be stable during calibrating. The calibration coefficient will be displayed in real-time, after the calibration is finished, it will be displayed in the text box on the right side. As shown in Figure 4-42, the parameters of calibration includes waveform type generated by signal source, waveform amplitude, frequency of signal source, calibrating time (generally 60s) and the error. Click "Begin" to start calibrating.



Figure 4-41

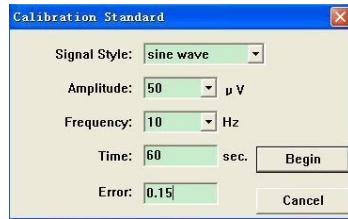


Figure 4-42

#### Function 20: Report Setup and Print

User can print the waveform and graphs in review and displaying interfaces as necessary, the operation instructions as below:

Click button on the toolbar, a dialogue box as shown in Figure 4-43 will appear, click "Ok" to print the BEAM or EEG waveform.

As shown in Figure 4-43, the print range is selectable, user can input the starting page and the ending page for printing; if you want to print the current page only, set the range to 1-1.

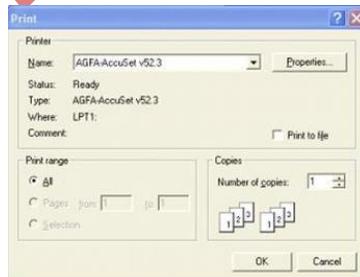


Figure 4-43

User can edit, view and print the report after data analyzing. Select menu “Print” -> “Print Report” or click button  to enter the interface as shown in Figure 4-44. Select menu “Print” -> “Report Setting” to edit the report, refer to Figure 4-45.

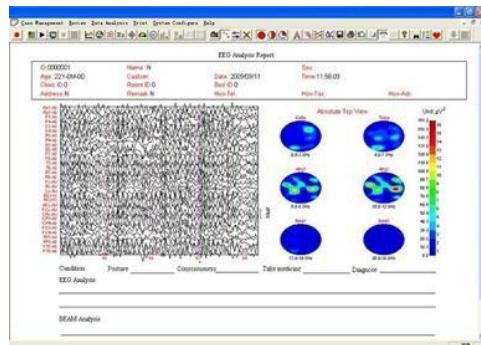


Figure 4-44

Click the edit area to input information: When editing, double click this area, you can use the terminologies that have been saved. Choose a term (after choosing, you can edit the term), then click the edit area again, the selected terminology is filled in automatically. Press “Enter” button or click other area to end the editing

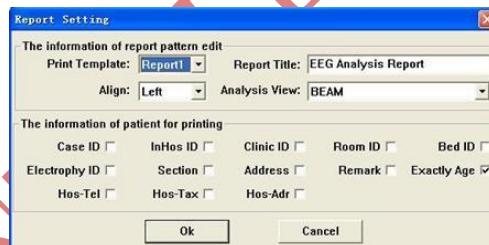


Figure 4-45

You can choose template, text align pattern, analysis view of report, edit the title and choose patient information to print out.

**⚠️ Notice:** It is recommended to set report template (select a template and patient information to be printed, edit the report title) first, and then edit content of report; Otherwise the system refreshing will empty the edited content.

#### Function 21: Output as Word File

Select the menu "Print" -> "Input Office WORD", it can import the template 1 of report into Office Word. Before using this function, please ensure you have installed the Microsoft Office.

## Function 22: Review/Extend Case

Select "Case Management" -> "Select Patient" or click button  to enter the interface as shown in Figure 4-46.

Click a case by left button of mouse, the patient information related to this case will be displayed on the right side; if there are many cases, you can search a case by inputting query conditions, the operation instructions as below:

Click the small box in front of "Search" to make the search function available to use, select the query condition and input the searching content, then click "Search" button, all cases satisfy the query conditions will be displayed in the list on left side. The system supports fuzzy search, for example, input patient's name as query condition, all cases with patient name containing the input query condition will be displayed. In addition, user can query by case ID to specify the search range. A prompt will appear if the system doesn't find any matched case. Click "Clear" to empty the input query conditions.

### 1. Review case

Select a case and click the "Open" button (or double click the case) to open it.

### 2. Extend case

Select a case and click "Extend Case" button to extend the case and enter gathering interface.

**Kindly reminder: In case reviewing, the "Modify Case Information" function is unable to use. User can edit the patient information in the "Patient List Management". If user opens the software the first time after software updating, it will automatically detect and update the cases of old version. If the case of old version is imported to the updated software and then used, it will not be applicable for the software that not updated. Therefore, it is recommended to backup the cases of old version.**

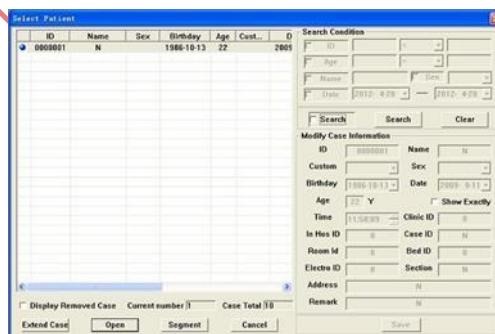


Figure 4-46

### **Function 23: Case library management**

Select menu "Case Management" -> "Patient List Management" to enter the interface as shown in Figure 4-47.

Select a case, modify the patient information of this case in the "Modify Case Information" area. Click "Save" button, a prompt will appear to remind user whether to save, then click "yes". Also, user can delete the unnecessary cases. Select the unwanted case and click "Delete" button to delete.

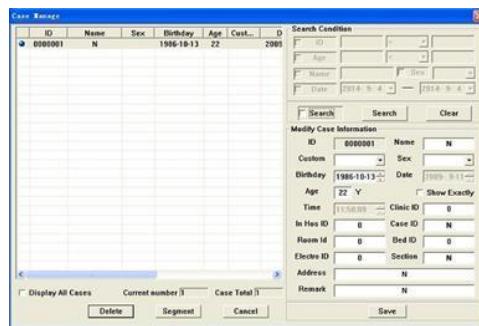


Figure 4-47

### **Function 24: Output/Input Case**

You can select "Case Management" -> "Case Input\Output" to save the case file in the folder names "EEG 18 ChannelCaseData" under appointed path.

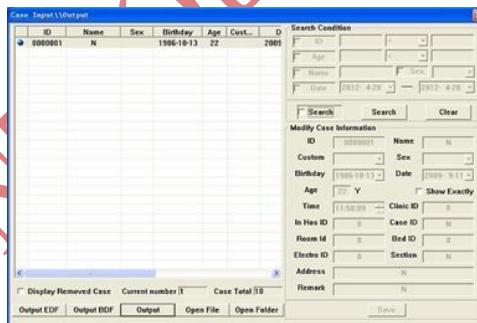


Figure 4-48

As shown in Figure 4-49, select the cases that you want to output and click "Output" button, then the system pops up a dialogue box to choose the file save path, after choosing, click "OK", a prompt dialogue box as shown in Figure 4-49 will appear, click "Yes" button to cut the case files, click "No" to copy, and click "Cancel" to give up outputting cases.



Figure 4-49

"Open File": select a case file (file format is \*.ifo) from other paths to import it to the current installation directory of the software, and add the case to the case list.

"Open Folder": select a folder from other paths to import all case files (file format is \*.ifo) in this folder to the current installation directory of the software, and add the cases to the case list.

"Output EDF": after clicking this button, it pops up a folder browsing dialogue box, choose the file save path, and click "OK", then a prompt dialogue box as shown in Figure 4-50 will appear, click "OK" button to convert the case to EDF format (operation of BDF format conversion is the same).



Figure 4-50

#### Function 25: Pathological waveform setup and detection

Select menu "Data Analysis" -> "Pathologic Analyse" or click button to enter the interface shown as Figure 4-51. Set the parameters of pathological waveform, and click "OK" to detect the pathological waveform, the detected waveform will be displayed in specified color.

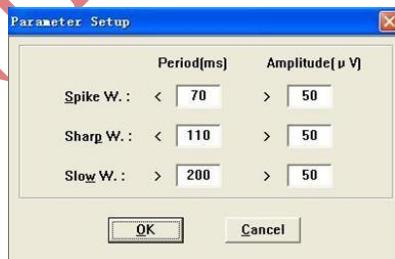


Figure 4-51

Select menu "System Configure" -> "Inspect Setting" or click to enter the interface shown as Figure 4-52, then user can set the colors of different pathological waveform.

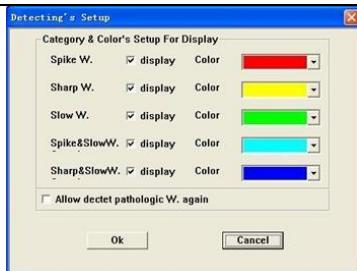


Figure 4-52

Choose appropriate color by clicking the drop-down menu for every waveform, make the "Allow detect pathologic W. again" selected, the system will process pathological waveform detection and display the detected pathological waveform by corresponding color.

#### Function 26: Language

When entering the system interface, choose "System Configure" -> "Language Select"

#### 4.5 Exit

In the interface shown as Figure 4-1, select "Case Management" -> "Exit" to exit the system. Turn off the computer and cut off the power.

## Chapter 5 Precautions

The device safety has been taken into consideration in product designing. But improper use may still cause electric shock or other injuries. In order to avoid accidents and ensure the device reliability, please obey the following requirements during use, installation and maintenance.

### Installation

1. Be careful with the cables and lines. The power cord and USB cable should not be tangled with other objects, and avoid from twisted and knotted.
2. A good ground wire (resistance  $\leq 4\Omega$ ) should be used for the computer. Do not use heating pipes or water pipe as temporary grounding cable, in order to avoid measurement error caused by improper grounding.
3. Do not cover or block the holes on the device, and do not place the device near heat source, otherwise the device may be damaged.

### Normal use

1. The device uses DC 5V as power source. If your power supply does not meet the requirement, contact our company please. The Digital Brain Electric Activity Mapping is a kind of precision equipment, please use original and matched power supply. If the voltage fluctuation is too large, it is recommended to use regulated power supply.
2. Do not push or push any object into the device enclosure, or spill liquid on the device to avoid liquid flows into the inner structure, then causing short circuit.
3. Do not use the device in humid environment. Disconnect the USB cable from the device when wiping away the dust. Do not use liquid detergent. It is available to use a cloth damped with water. If the device will not be used for long time or when it rains and thunders, be sure to unplug the power cord from the outlet.
4. All kind of cables of the device should be used correctly according to the requirement, refer to the method of connecting the device and patient and its operation instructions.
5. If the device must be used connecting with other equipment, only the equipment that belongs to the Class I equipment of standard GB9706.1 can be connected. As leakage current may hurt the patient, it should be mentioned on the connected equipment, and the equipment assumes relevant responsibilities.
6. When the device is used together with a electric surgical device, all electrodes on the patient should be removed, otherwise the electrodes may burn out. Refer to the operation instructions of the electric surgical device for details.

## Maintenance

1. Do not disassemble the device enclosure without authorization. If necessary, the device should be maintained by a professional-technical personal.
2. In the following situations, disconnect the USB cable from the device and contact the technical personnel of our company:
  - a. The cables and plugs are damaged;
  - b. Foreign object falls into the device or liquid flows into the device;
  - c. The device doesn't work under correct operations.
3. Use soap or clean water to clean the lead cables, and use ethanol-based or acetaldehyde-based solutions to sterilize. If the lead cable is damaged or the clamps are rusty, please contact our company to replace the lead cables.
4. Use clean water to clean the electrodes, water temperature should be lower than 50°C, and the soaking time should not be longer than 1h. Use ethanol-based or acetaldehyde-based solutions for sterilization. If the electrodes are rusty, please contact our company to replace the electrodes.
5. The device and its parts should be inspected regularly (at least once per 6 months).
6. The scope of warranty does not cover the following situations: modification, disassembly, re-installation or repair prior to the permission of the manufacturer; or loss due to negligence or accident; or improper installation or application; or original identification mark is removed.

## Experience in Use and Maintenance

The operating habits and maintenance levels of the operator not only affect the service life of the device, but also directly relate to the quality of the detected waveform and diagnostic quality. Through the problems encountered by technical engineers in the process of installation and maintenance, we have accumulated a lot of experience to share with you. The amplitude of brain waves measured by EEG products is very low, generally around tens of microvolts, which is a weak signal. So whether in the installation or maintenance process, first check the following aspects:

1. The surrounding environment and the location of the device. The device should be installed in a quiet environment, away from physiotherapy room that generating X-ray or ultra-short wave, substation, construction site and large mechanical room. Considering the convenience of use, choose the location close to neurology clinic or ward. In a high-rise building, it is recommended to install the device on the second or third floor. In addition, the device should be placed in a cool and dry place, and keep the room clean. Do not put it

- under the window or near radiator to prevent heat and moisture. It is better to equip with air conditioning facilities in the EEG room.
2. Ground wire. The Brain Electric Activity Mapping is a sophisticated electronic instrument that requires a good ground wire to ensure the normal operation of the device and personal safety. A special ground wire should be used, usually, it is a copper rod with a diameter of 1.0 ~ 1.5cm, or a copper plate with a size of 40cm\*40cm and a thickness of 2 ~ 4mm buried in the underground of 1.0 ~ 1.5m deep. Place some water-absorbing substances (such as charcoal) and salt around it to reduce the electrical resistivity of the soil, and keep the ground wire in good contact with the land. The other end of the ground wire is tightly welded to a thick steel wire of 80 ~ 100cm, and then connected to the casing of the device. After the device is grounded, use a grounding resistance tester to check whether the grounding resistance meets the requirement (less than  $4\Omega$ ). If it exceeds the specified value, re-install and debug the ground wire.
  3. Power supply. The power supply of the EEG room should be supplied by a dedicated line from the power distribution room to obtain stable voltage during using.
  4. Patient. Before the EEG examination, the clinician should have a detailed understanding of the patient's relevant information and medication. Critically ill patient should be accompanied by a special person for the induction experiment. Excessive scalp oil and large resistance on scalp electrode often lead to low brain wave amplitude and big interference. Therefore, it is recommended to wash patient's hair before the examination. Low blood sugar can also affect the EEG results, do not fasting, and the examination is appropriate after three hours of eating.
  5. Electrodes. The electrodes should be placed in strict accordance with the international 10-20 system. Patient's hair should be parted to ensure good contact between the electrodes and the scalp. If the waveform is asymmetrical left and right, and the waveform on one side appears abnormal and large interference, first check the placement of the ear electrode on corresponding side.
  6. Communication cable. Check the communication cable when data communication fails. If there is any problem, replace the communication cable.
  7. User should properly dispose of the scrapped products and packaging materials following the local laws and regulations, and try to support the classification and recycling.
  8. The schematic diagram and component list related to the device can only be provided to the qualified service station or maintenance staff approved by our company. The maintenance personnel is responsible for maintaining our device.

- ◆ **Do not run other programs during waveform gathering, and close the floating windows (such as input method window) to avoid affecting the waveform gathering.**
- ◆ **When not all leads are connected:**

All lead cables should be connected to the corresponding lead in the gathering. If only some of the leads are necessary, please be sure to short all unconnected lead cables by metal wires, and then connect with the GND to eliminate the interference signals introduced by the unconnected lead cables. At the same time, the unconnected lead should be closed in the software correspondingly (click the lead name on the right side of the waveform, the waveform of this lead turns to a straight line), in order to prevent its fluctuation from affecting other leads.

## Chapter 6 Troubleshooting

| Problems   | Causes   | Solutions   |
|--|--|---|
| The indicator does not light, the prompt for drive installation does not appear.                                     | 1. The USB cable is loose or not inserted correctly.<br>2. The USB interface is damaged.<br>3. The USB cable is damaged. | 1. Ensure the USB cable is inserted correctly.<br>2. Replace the USB interface.<br>3. Replace the USB cable.  |
| The software prompts “Please check the line of communication!”   | 1. The amplifier is not well connected.<br>2. Hardware drive is not installed.<br>3. The USB cable is damaged.           | 1. Check the connection of cables and ensure that the indicator is lighting.<br>2. When computer connects with the amplifier for the first time, it will pop up a drive installation prompt, please follow the steps to install the drive.<br>3. Replace the USB cable. |
| Strobe light does not work   | 1. The device is not connected to power source.<br>2. USB data line is not used.<br>3. Operation procedure is wrong.     | 1. Connect the power source correctly to ensure normal power supply.<br>2. The strobe light should be connected with the computer by a USB data line.<br>3. Check the connection between each part before running the software.   |
| During normal gathering, waveform of all leads turn to straight lines suddenly, and the time displayed is incorrect. | USB cable is loose.  | Insert the USB cable well, then restart the software.   |
| Large interference of EEG  | 1. Ground wire is not well connected.<br>2. Electrode is rusted.   | 1. Connect the ground wire according the requirement, and tighten it with the ground wire plug on the back the host.  |

|  |  |   |
|--|--|---|
|  | <p>3. Clamp of lead cable is rusted.</p> <p>4. Lead cable is broken.</p> <p>5. Patient's scalp is dirty or electrode is clamped on the hair.</p> | <p>2. Replace the electrode and lead cable.</p> <p>3. Replace the lead cable.</p> <p>4. Clean the skin before wearing the electrodes.</p>   |
| Large interference on one side   | The ear electrode on the side with large interference is not worn properly.  | Wear the ear electrode correctly.   |
| Large interference, low amplitude or even straight line appears on one lead or several leads | <p>1. Poor electrode contact.</p> <p>2. Lead cable are knotted or entangled with each other.</p>   | <p>1. Wear the electrodes properly.</p> <p>2. Smooth the lead cables.</p>   |
| The printer does not work.   |  | Refer to the operation instructions of printer.   |
| The print's color is too light or not clear.   | The ink is used up.  |   |
| The printer does not respond when the print button is pressed.                               | <p>1. The cable of printer falls off.</p> <p>2. The cable of printer is damaged.</p> <p>3. Program error</p>                                     | <p>1. Insert the cable of printer tightly.</p> <p>2. Replace the cable of printer.</p> <p>3. Turn off the printer and computer, restart the printer first, then turn on the computer.</p> |

## Chapter 7 Principle

BEAM is a new method to analyze brain bioelectricity followed the development of computer technology and computer image processing technology. As a new technology, by computer processing, it transforms a large number of complex and irregular brain bioelectricity to the image form which can reflect quantitative change and position, which displays the condition of brain function change visually and conspicuously. In the diagnosis of intracranial lesions and the treatment of functional neurosurgical, it is necessary to correctly evaluate the patient's brain function by applying this technology.

### Principle and method

1. Placement of electrode: place 16 electrodes on scalp according to international 10-20 system method, then collect brain wave signals to perform A/D conversion.
2. Fourier Transform: via computer processing, transform the 16 brain wave signals collected to the form of power spectrum to display the relation of brain frequency domain and power.
3. Frequency classification:
  - δ frequency band: 0.8–3.8 Hz
  - θ frequency band: 4.0–7.8 Hz
  - α<sub>1</sub> frequency band: 8.0–9.8 Hz
  - α<sub>2</sub> frequency band: 10.0–12.8 Hz
  - β<sub>1</sub> frequency band: 13.0–19.8 Hz
  - β<sub>2</sub> frequency band: 20.0–30.0 Hz
4. **Interpolation operation:** according to the values of known 16 points, find an interpolation function to the brain wave power outside the 16 points in accordance with the principle of two-dimensional interpolation, then calculate the value of 2500 points, the interpolation formula is as following:

$$\sum_{m=1}^5 \sum_{n=1}^5 = (m/5 \times n/5) \times \frac{\sin(X - m/5) \times \sin 5\pi(Y - n/5)}{5\pi(X - m/5) \times 5\pi(Y - n/5)}$$

5. After the equipotential map is obtained, print the values obtained to frequency-brain picture by the printer to get the power spectrum map. Brain wave signal collected is amplified by the electroencephalograph, then input the signal to the computer for A/D convention and Fourier transform.

### Result analysis: power is divided into 16 levels.

1. Power spectrum map for normal adult

### 6 maps according to spectrum classification

- 
- ① δ wave map: 3–5 level in each area of brain generally, up to 8 level for double.
  - ② θ wave map: symmetrical on two sides basically, 6–8 level for frontal part, on midfrontal for some normal people.
  - ③ α wave map: ( $\alpha_1$  and  $\alpha_2$ ) the highest part for power is occipital and top part, power is up to 16 level, it is 10 and 16 level generally, symmetrical on two sides for most people, but it can not exceed 5 or 8 level.
  - ④ β wave map: ( $\beta_1$  and  $\beta_2$ ) symmetrical and uniform on two sides, below 7 level generally.
2. Abnormal map
- ① It is abnormal when part power of δ wave map exceeds the normal value of 8 level or more.
  - ② It is abnormal when the power spectrum of θ wave map is in local parts or whole brain exceeds the normal value of 10 level or more.
  - ③ It is abnormal when obvious asymmetric phenomenon appears on the two sides of α wave map, and the power exceeds 3 level or more or 5 level.
  - ④ It is abnormal when asymmetric phenomenon appears on the two sides of β wave map, and the power exceeds 3 level, abnormal increase for power is over 6 level or more.
3. Power spectrum map for patient

Most of the patient's spectrum map is abnormal, the power of δ wave and θ wave increase (especially it is evident for the first half of the brain), with the increase of power of  $\alpha_2$  (namely slow α wave) wave, β wave also has the trend of increase.

## Chapter 8 Transport and Storage

Transport: the packed device can be transported by ordinary conveyance. During transport, it can not be transported mixed with toxic, harmful, corrosive material.

Storage: the packed device should be stored in room with no corrosive gases and good ventilation.

Temperature: -20 °C ~ +55 °C; Relative humidity: ≤ 90%.

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## Chapter 9 Appendix (Placement of Electrodes)

### Placement of electrode

There are following basic principles in international standard:

- ① The position of electrode should be determined according to the measurement of skull mark, when measuring, it should preferably proportionate to the size and shape of skull.
- ② The standard position of electrode should be properly distributed on all parts of skull (it may not be used fully in one experiment).
- ③ The name of electrode position should combine brain region (such as temple, top).
- ④ Anatomical study should be performed to determine which cortical division it locates under these standard electrode positions for the general human.

Placement position of electrode should be performed strictly in accordance international 10-20 system (as Figure 9-1), the following Figure shows the positions of all electrodes in international 10-20 system.

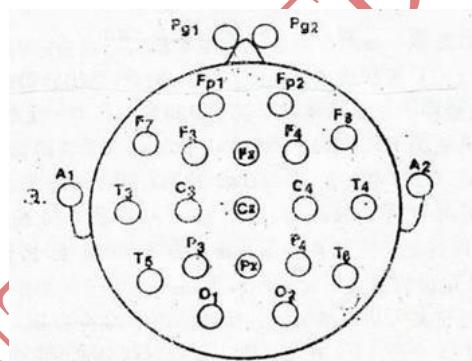


Figure 9-1

According to International EEG Society's advice, the international 10-20 system electrode placement method adopted commonly at home and abroad, it properly places 21 electrodes (including 2 ear electrodes) to all parts of skull (as Figure 9-2) through the sagittal line, the coronal line and the temporal lateral line.

- ① Sagittal line: make a sagittal line from Nasion N to Inion I and set it to 100%, mark 5 points from N-I to name as FP1 (Frontal pole), FZ (Frontal zero), CZ (Central zero), PZ (Parietal zero) and O (Occipital). N-FP and I-O, each of them is 10% of the total length of its line, the remaining points are respectively 20% of the total length of its line. The naming of 10-20 electrode placement method is derived from here.

② Coronal line: make a line from left intertragic incisure via Cz to right intertragic incisure, the whole length is 100%, mark 5 points from left intertragic incisure to right intertragic incisure to respectively name as T3 (Left Temporal), C3 (Left Central), Cz, C4 (Right Central) and T4 (Right Temporal). The distance from left intertragic incisure-T3 and right intertragic incisure-T4 is 10% of the total length of its line, the remaining points are respectively 20% of the total length of its line.

③ Temporal lateral line: make a line from FP to O, the line parallels with Nasion-N-Intertragic incisure-Inion line, the whole length is 100%, mark 5 points from FP-O to respectively name as FP1 (Fp1F2), F7 (Inferior Frontal), T3 (T4) and T5 (T6) (Posterior temporal), the distance from FP-T3 (Fp1F2) and O-O1 (O2) is 10% of the total length of its line, the remaining points are respectively 20% of the total length of its line.

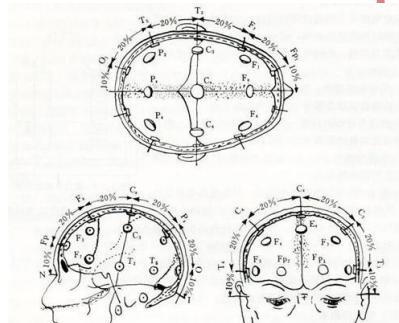


Figure 9-2

According to international practice, the left side is odd number, right side is even number, 0 line represents a central position, A1 and A2 are left and right ear lobe, the concrete placement of electrode is as following (take C4 electrode as an example).

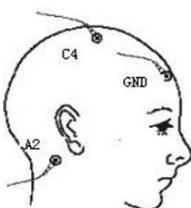


Figure 9-3

A2 is the reference electrode of right ear, which can also be placed on lobe, GND(A) is a ground electrode located on the center of forehead, C4 is the right central electrode, other electrodes are placed similarly.

## Chapter 10 Accessories

### 10.1 Accompanying Accessories

| Host                    | Display                     | Keyboard         | Printer            | Dedicated strobe simulator |
|-------------------------|-----------------------------|------------------|--------------------|----------------------------|
| 1 pc                    | 1 pc                        | 1 pc             | 1 pc               | 1 set                      |
| <b>Lead cables</b>      | <b>Electrodes</b>           | <b>Hat</b>       | <b>Ground Wire</b> | <b>Electrode bracket</b>   |
| 1 set                   | 1 set                       | 2 pcs            | 1 pc               | 1 set                      |
| <b>Cable of printer</b> | <b>Multi-purpose socket</b> | <b>Amplifier</b> |                    |                            |
| 1 pc                    | 1 pc                        | 1 pc             |                    |                            |

### 10.2 Notes

- 10.2.1 Please follow the instructions on the package when opening the package.
- 10.2.2 After unpacking, please check the accessories and accompanying documents in accordance with the packing list, then start inspecting the device.
- 10.2.3 If the packaging content does not meet the requirement or the device does not work properly, please contact our company immediately.
- 10.2.4 Please use the accessories provided by our company, otherwise the performance and safety of the device may be affected. If accessories provided by other company need to be used, please first consult the after-sales service of our company, or we will not responsible for any caused damages.
- 10.2.5 The package shall be kept properly for future use in regular maintenance or device repair.

## Appendix EMC Compatibility Requirements

Table 1: Electromagnetic emission

| Guidance and manufacturer's declaration – electromagnetic emission  |            |   |
|---|------------|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. |            |   |
| Emission test   | Compliance | Electromagnetic environment - guidance  |
| RF emissions GB 4824  | Group 1    | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.   |
| RF emissions GB 4824  | Class B    | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions GB 17625.1   | —          |   |
| Voltage fluctuations / flicker emission GB 17625.2  | Complies   |   |

Table 2: Electromagnetic immunity 1

| Guidance and manufacturer's declaration – electromagnetic immunity  |  |  |  |
|---|--|--|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. |  |  |  |
| Immunity test   | IEC60601 test level                            | Compliance level                               | Electromagnetic environment – guidance   |
| Electrostatic discharge (ESD) GB/T 17626.2  | ±6kV contact ±8kV air                          | ±6kV contact ±8kV air                          | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst GB/T 17626.4  | ±2kV for power supply lines ±1kV for I/O lines | ±2kV for power supply lines ±1kV for I/O lines | Mains power quality should be that of a typical  |

|   |   |   |  |
|---|---|---|--|
|   |   |   | commercial or hospital environment.  |
| Surge GB/T 17626.5  | $\pm 1\text{kV}$ lines to lines<br>$\pm 2\text{kV}$ lines to earth  | $\pm 1\text{kV}$ lines to lines<br>$\pm 2\text{kV}$ lines to earth  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>GB/T 17626.11 | <5% Ut(>95% dip in Ut) for 0.5 cycle<br>40% Ut(60% dip in Ut) for 5 cycle<br>70% Ut(30% dip in Ut) for 25 cycle<br><5% Ut(>95% dip in Ut) for 5 sec | <5% Ut(>95% dip in Ut) for 0.5 cycle<br>40% Ut(60% dip in Ut) for 5 cycle<br>70% Ut(30% dip in Ut) for 25 cycle<br><5% Ut(>95% dip in Ut) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50 Hz) magnetic field<br>GB/T 17626.8  | 3 A/m   | 3 A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |

NOTE Ut is the a.c. mains voltage prior to application of the test level.

Power frequency magnetic field: Turn on the 80Hz low-pass filter

Table 3: Electromagnetic immunity 2

| Guidance and manufacturer's declaration-electromagnetic immunity  |                     |                  |  |
|---|---------------------|------------------|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. |                     |                  |  |
| Immunity test   | IEC60601 test level | Compliance level | Electromagnetic environment – guidance |

|   |   |                        |  |
|---|---|------------------------|--|
|   |   |                        | <p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2 \sqrt{P} \text{ 80 MHz-800 MHz}$ $d = 1.2 \sqrt{P} \text{ 800 MHz-2.5 GHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz-2.5 GHz}$ <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the standard. transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| Conducted<br>RF<br>GB/T<br>17626.6  | 3V(effective<br>value)<br>150 kHz-80<br>MHz | 3V(effective<br>value) |  |
| Radiated<br>RF<br>GB/T<br>17626.3   | 3 V/m<br>80 MHz-2.5<br>GHz                  | 3 V/m                  |  |
| <p>NOTE 1 At 80MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>   |   |                        |  |
| <ul style="list-style-type: none"> <li>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to</li> </ul> |   |                        |  |

verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended Separation Distances

| Recommended separation distances between portable and mobile RF communications equipment and the Digital Brain Electric Activity Mapping   |   |                                       |  |
|--|---|---------------------------------------|--|
| Rated maximum output power of transmitter (W)  | Separation distance according to frequency of transmitter (m) |                                       |  |
|  | 150 kHz – 80 MHz<br>$d = 1.2\sqrt{P}$                         | 80 MHz – 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz – 2.5 GHz<br>$d = 1.2\sqrt{P}$ |
| 0.01   | 0.12  | 0.12                                  | 0.23                                   |
| 0.1  | 0.38  | 0.38                                  | 0.73                                   |
| 1  | 1.2   | 1.2                                   | 2.3                                    |
| 10   | 3.8   | 3.8                                   | 7.3                                    |
| 100  | 12  | 12                                    | 23                                     |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. |   |                                       |  |
| NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.   |   |                                       |  |
| NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |   |                                       |  |

**WARNING**

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

The following cable types must be used to ensure that they comply with interference radiation and immunity standards:

| No. | Name                                | Cable length<br>(m) | Shielding | Remark |
|-----|-------------------------------------|---------------------|-----------|--------|
| 1   | 2 USB data lines (USBAM to USBBM)   | 3.0                 | No        | /      |
| 2   | EEG lead cable                      | 1.0                 | No        | /      |
| 3   | Power adapter cable of strobe light | 1.0                 | No        | /      |

Table 5: Cable Overview

**WARNING**

The ME EQUIPMENT or ME SYSTEM should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ME EQUIPMENT or ME SYSTEM should be observed to verify normal operation in the configuration in which it will be used.

**WARNING**

Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.

**WARNING**

Portable and mobile RF equipment may affect the use of medical electrical equipment.

Basic performance description: When the device is set to measuring state, it could work normally under required technical requirements. The waveform noise and error appeared during measuring could eliminate automatically 10s after the interference stopped, and the saved data is not lost.

For the equipment without a manual sensitivity adjustment and for which the manufacturer specifies a minimum amplitude or value of the patient physiological signal, the device should describe the minimum amplitude or value of patient physiological signal, which is 0.1  $\mu$ V.

**WARNING**

Po Operating the device or system below the minimum amplitude or minimum value may result in inaccurate results.

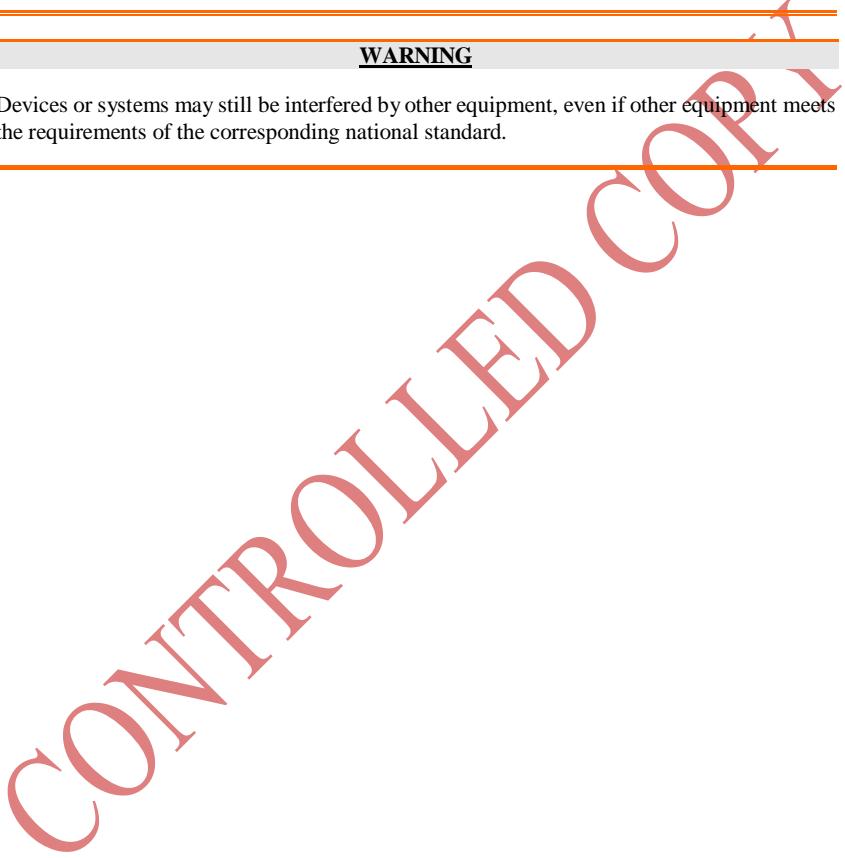
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**WARNING**

Devices or systems may still be interfered by other equipment, even if other equipment meets the requirements of the corresponding national standard.

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| <b>PT. SINKO PRIMA ALLOY</b>            |  |
|---|--|
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| SPA-BM/PROD-238. 29 Agustus 2025. Rev00 |  |